

REMARKS

This is in response to the Office Action mailed October 19, 2005. Currently pending are claims 1-47 and 49-52. In the Action, the claims were subject to an election of species requirement and the Examiner has required the Applicants to elect from various subspecies.

In response to the restriction/election requirement, the Applicants elect with traverse species 5 wherein the primer layer comprises a cross-linkage polymer and anchoring polymer, subspecies 1 wherein the drug releasing layer comprises stabilizing polymer, sub-subspecies 2 wherein the active agent is selected from group 2, and sub-sub-subspecies 1 having an intermediate layer. Claims 1-14, 16-24, 26, 28-30, 32-42, 46-47, and 49-52 are readable on all of the elected species, subspecies, sub-subspecies and sub-sub-subspecies. Should the examiner find the elected species patentable, it is then respectfully requested that the non-elected species be examined. The Applicants reserve the right to file a divisional application to all claims withdrawn, cancelled or restricted out. The Applicants elect these embodiments with traverse.

Applicants submit that the restriction requirement is improper and should be withdrawn. The Examiner asserts that a further restriction is made because the application contains claims directed to patentably distinct species and subspecies. The Examiner restricts the primer layer polymers into species 1 relating to cross-linkage polymers, species 2 relating to hydrophobic polymers, species 3 relating to hydrophilic polymers, species 4 relating to anchoring polymers and species 5 relating to cross-linkage polymers and anchoring polymers and the drug releasing layer into subspecies 1 relating to stabilizing polymer, subspecies 2 relating to toughening polymers, subspecies 3 relating to hydrophilic polymers and subspecies 4 relating to ionic complexes.

However, as set forth in MPEP 806.04(f), "[c]laims to be restricted to different species must be mutually exclusive." In the present case, the species set forth by the Examiner are not mutually exclusive. As exemplified in claim 1, the primer layer and the drug reservoir layer each require two or more polymers that may comprise more than one type of polymer, i.e., a hybrid polymer layer (e.g., paragraph 48 of the specification). See also, paragraph 16, wherein the "inventive coatings use a primer system with at least two polymers, preferably a hydrophilic and a hydrophobic polymer." Therefore, it is improper to restrict the layer to only one type of polymer.

In addition, the Examiner's categorizations of species and subspecies listings are inconsistent. If the invention was restricted to one type of polymer, then the Examiner cannot preclude another species that the polymer fits into. First, the Examiner restricts cross-linkage polymer and anchoring polymer into species 1 and 4, respectively, but then combines these two types of polymers into species 5. Second, a polymer may be fit into more than one type of category, e.g., a polymer may be a hydrophobic anchoring polymer. For example, the primer layer may comprise acrylate/carboxyl polymer (*hydrophobic anchoring polymer*), epoxy polymer (*cross-linkage polymer*) and polyvinylpyrrolidone vinylacetate copolymer (PVP/VA) (*hydrophilic polymer*) (e.g., paragraph 91, claim 28 and Example 1) or ethylene acrylic acid copolymer (EAA) (*hydrophobic anchoring polymer*), epoxy polymer (*cross-linkage polymer*), and polycarbonate urethane (*hydrophilic polymer*) (e.g., paragraph 0092, claim 29 and Examples 1-4 and 6-14). Similarly, for example, the drug release layer may comprise nitrocellulose (*stabilizing hydrophobic polymer*) and polytetramethylene ether glycol urethane (*hydrophilic toughening polymer*) (e.g., paragraph 95, claim 33 and Examples 2-10).

Applicants also disagree with the Examiner's contention that no claim is generic. Claim 1 is generic and reads upon all species, subspecies, sub-subspecies and sub-sub-subspecies, and "include[s] no material element additional to those recited in the species claims, and [comprehends] within its confines the organization covered in each of the species." MPEP 806.04(d). Furthermore, "a claim may include two or more of the disclosed embodiments within the breadth and scope of the definitions (and thus be designated a generic or genus claim). MPEP 806.04(e). Claim 1 meets all of these definitions of a generic claim.

Applicants further contend that the Examiner has not met the burden of proving that the referenced groupings of species and subspecies are distinct and separate and will place a serious burden on the Examiner. MPEP 1504.05 and 803(A) and (B). The Examiner is required to show by appropriate explanation that there will be a serious burden on the Examiner to search the related art because of a separate classification, a separate status in the art, or a different field of search as defined in MPEP 808.02. The Examiner has not done so.

Furthermore, if the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions. MPEP 803.02. The Applicants contend that embodiments listed in the dependent claims are sufficiently few and are closely related that a search and examination of the claims in their entirety would not be a serious burden on the examiner.

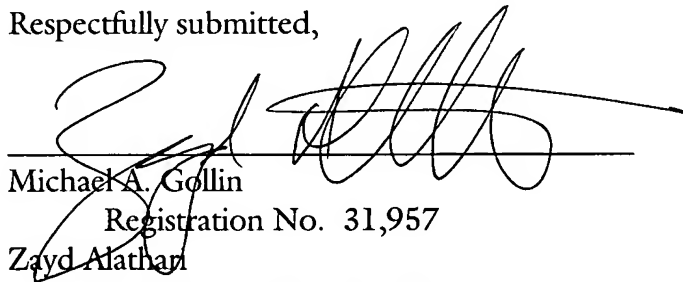
For at least these reasons, the Applicants respectfully traverse the restriction requirement, request that the restriction requirement be withdrawn and submit that all the claims should be examined.

Applicants further submit that the claims are in condition for allowance and request that the Examiner so indicate and issue a notice of allowability and that the application be passed to issue.

It is believed that this response is a complete reply to the restriction requirement and thus Applicants respectfully request that prosecution proceed. Should the Examiner have any questions which might be amenable to a telephone interview, the Examiner is invited to contact undersigned counsel to discuss such issues. If any additional fee is required in conjunction with this response, the Commissioner is authorized to charge our deposit account No. 22-0261, and notify undersigned counsel accordingly.

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Respectfully submitted,



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